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# ANNUAL SUBJECT INDEX OF ARTICLES

JANUARY THROUGH DECEMBER 1985

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**E**ach listing shows the title of a major article or short article, the latter in italics. The first two figures following the title indicate the date of the issue, and the last figure indicates the number of the page upon which the article begins. MEDICAL ECONOMICS will send physicians any three articles listed on these pages without charge. Photocopies of articles longer than six pages are priced at \$1.50. Whole copies of the magazine (including special issues) may be purchased for \$3.00 each from the Reader Service Department as long as the supply lasts.

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## Transderm-Nitro®

(nitroglycerin)

### Transdermal Therapeutic System

BRIEF SUMMARY (FOR FULL PRESCRIBING INFORMATION, SEE PACKAGE INSERT)

#### INDICATIONS AND USAGE

This drug product has been conditionally approved by the FDA for the prevention and treatment of angina pectoris due to coronary artery disease. The conditional approval reflects a determination that the drug may be marketed while further investigation of its effectiveness is undertaken. A final evaluation of the effectiveness of the product will be announced by the FDA.

#### CONTRAINDICATIONS

Intolerance of organic nitrate drugs, marked anemia, increased intraocular pressure or increased intracranial pressure.

#### WARNINGS

In patients with acute myocardial infarction or congestive heart failure, Transderm-Nitro system should be used under careful clinical and/or hemodynamic monitoring. In terminating treatment of anginal patients, both the dosage and frequency of application must be gradually reduced over a period of 4 to 6 weeks to prevent sudden withdrawal reactions, which are characteristic of all vasodilators in the nitroglycerin class. Transdermal nitroglycerin systems should be removed before attempting defibrillation or cardioversion because of the potential for altered electrical conductivity which may enhance the possibility of arcing, a phenomenon associated with the use of defibrillators.

#### PRECAUTIONS

Symptoms of hypotension, such as faintness, weakness or dizziness, particularly orthostatic hypotension may be due to overdose. When these symptoms occur, the dosage should be reduced or use of the product discontinued. Transderm-Nitro system is not intended for immediate relief of anginal attacks. For this purpose occasional use of the sublingual preparations may be necessary.

#### ADVERSE REACTIONS

Transient headaches are the most common side effect, especially when higher doses of the drug are used. These headaches should be treated with mild analgesics while Transderm-Nitro therapy is continued. When such headaches are unresponsive to treatment, the nitroglycerin dosage should be reduced or use of the product discontinued. Adverse reactions reported less frequently include hypotension, increased heart rate, faintness, flushing, dizziness, nausea and vomiting. These symptoms are attributable to the known pharmacologic effects of nitroglycerin, but may be symptoms of overdose. When they persist the dose should be reduced or use of the product discontinued. In some patients, dermatitis may occur.

#### DOSEAGE AND ADMINISTRATION

Therapy should be initiated with application of one Transderm-Nitro 5 system to the desired area of skin. Many patients prefer the chest; if hair is likely to interfere with system adhesion or removal, it can be clipped prior to placement of the system. Each system is designed to remain in place for 24 hours, and each successive application should be to a different skin area. Transderm-Nitro system should not be applied to the distal parts of the extremities.

The usual dosage is one Transderm-Nitro 5 system every 24 hours. Some patients, however, may require the Transderm-Nitro 10 system. If a single Transderm-Nitro 5 system fails to provide adequate clinical response, the patient should be instructed to remove it and apply either two Transderm-Nitro 5 systems or one Transderm-Nitro 10 system. More systems may be added as indicated by continued careful monitoring of clinical response. The Transderm-Nitro 2.5 system is useful principally for decreasing the dosage gradually, though it may provide adequate therapy for some patients when used alone.

The optimal dosage should be selected based upon the clinical response, side effects, and the effects of therapy upon blood pressure. The greatest attainable decrease in resting blood pressure that is not associated with clinical symptoms of hypotension especially during orthostasis indicates the optimal dosage. To decrease adverse reactions, the size and/or number of systems should be tailored to the individual patient's needs. Do not store above 86°F (30°C).

#### PATIENT INSTRUCTIONS FOR APPLICATIONS

A patient leaflet is supplied with the systems.

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## TAGAMET® brand of CIMETIDINE

Before prescribing, see complete prescribing information in SK&F LAB CO. literature or *PDR*. The following is a brief summary.

**Indications:** Tagamet® (brand of cimetidine) is indicated in the short-term treatment of active duodenal ulcer; in prophylactic use, at reduced dosage, to prevent recurrent duodenal ulcer in patients likely to need surgical treatment, such as those with a history of recurrence or complications and those with concomitant illness in whom surgery would constitute a greater than usual risk (limitation to this population is recommended because the consequences of use beyond one year of continuous Tagamet® therapy are not known); in the short-term treatment of active benign gastric ulcer (there is no information concerning usefulness of treatment periods of longer than 8 weeks); and in the treatment of pathological hypersecretory disorders (i.e., Zollinger-Ellison syndrome, systemic mastocytosis and multiple endocrine adenomas). In active duodenal ulcer, concomitant antacids should be given as needed for relief of pain; however, simultaneous administration is not recommended. **Contraindications:** There are no known contraindications to the use of Tagamet®.

**Precautions:** While a weak antiandrogenic effect has been demonstrated in animals, Tagamet® has been shown to have no effect on spermatogenesis, sperm count, motility, morphology or *in vitro* fertilizing capacity in humans.

In a 24-month toxicity study in rats at dose levels approximately 9 to 56 times the recommended human dose, benign Leydig cell tumors were seen. These were common in both the treated and control groups, and the incidence became significantly higher only in the aged rats receiving Tagamet®.

Rare instances of cardiac arrhythmias and hypotension have been reported following the rapid administration of Tagamet® HCl (brand of cimetidine hydrochloride) injection by intravenous bolus.

Symptomatic response to Tagamet® therapy does not preclude the presence of a gastric malignancy. There have been rare reports of transient healing of gastric ulcers despite subsequently documented malignancy.

Reversible confusional states have been reported on occasion, predominantly in severely ill patients.

Tagamet® has been reported to reduce the hepatic metabolism of warfarin-type anticoagulants, phenytoin, propranolol, chlorazepate, diazepam, lidocaine, theophylline and metronidazole. Clinically significant effects have been reported with the warfarin anticoagulants; therefore, close monitoring of prothrombin time is recommended, and adjustment of the anticoagulant dose may be necessary when Tagamet® is administered concomitantly. Interaction with phenytoin, lidocaine and theophylline has also been reported to produce adverse clinical effects.

Lack of experience to date precludes recommending Tagamet® for use in pregnant patients, because of childbearing potential, nursing mothers or children under 16 unless anticipated benefits outweigh potential risks; generally, nursing should not be undertaken in patients taking the drug since cimetidine is secreted in human milk. Decreased white blood cell counts have been reported in Tagamet®-treated patients who also received drugs and/or treatment known to produce neutropenia.

**Adverse Reactions:** Diarrhea, dizziness, somnolence, headache, rash, gynecomasia. Reversible arthralgia, myalgia and exacerbation of joint symptoms in patients with preexisting arthritis have been reported. Reversible confusional states (e.g., mental confusion, agitation, psychosis, depression, anxiety, hallucinations, disorientation), predominantly in severely ill patients, have been reported. Reversible impotence in patients with preexisting hypogonadal disorders receiving Tagamet®, particularly in high doses, for at least 12 months, has been reported. Reversible alopecia has been reported very rarely. Decreased white blood cell counts in Tagamet®-treated patients (approximately 1 per 100,000 patients), including agranulocytosis (approximately 3 per million patients), have been reported, including a few reports of recurrence on rechallenge. These patients generally had serious concomitant illnesses and received drugs and/or treatment known to produce neutropenia. Thrombocytopenia (approximately 3 per million patients) and a few cases of aplastic anemia have also been reported. Increased serum transaminase and creatinine, as well as rare cases of fever, interstitial nephritis, urinary retention, pancreatitis and allergic reactions, including hypersensitivity vasculitis, have been reported. Reversible adverse hepatic effects, cholestatic or mixed cholestatic-hepatocellular in nature, have been reported rarely. Because of the predominance of cholestatic features, severe parenchymal injury is considered highly unlikely. A single case of biopsy-proven peripartur hepatic fibrosis in a patient receiving Tagamet® has been reported.

**How Supplied:** Pale Green Tablets: 300 mg. tablets in bottles of 100; 300 mg. tablets in bottles of 100 and Single Unit Packages of 100 (intended for institutional use only); 400 mg. tablets in bottles of 60 and Single Unit Packages of 100 (intended for institutional use only). Liquid: 300 mg./5 mL. in 8 fl. oz. (237 mL) amber glass bottles and in single-dose units (300 mg./5 mL.), in packages of 10 (intended for institutional use only). Injection: 300 mg./2 mL. in single-dose vials and in 8 mL. multiple-dose vials, in packages of 10, and in single-dose, prefilled disposable syringes.

Date of issuance: Aug. 1985

BRS-TC-159

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**SK&F LAB CO.** Carolina, P.R. 00630

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**Brief Summary:** ANAPROX® (naproxen sodium)  
**Indications:** Relief of mild to moderate pain; treatment of primary dysmenorrhea.

**Contraindications:** Patients who have had allergic reactions to NAPROSYN or ANAPROX or in whom aspirin or other NSAIDs induce the syndrome of asthma, rhinitis, and nasal polyps.

**Warnings:** GI bleeding, sometimes severe, and occasionally fatal, has been reported. Do not give to patients with active peptic ulcer unless potential benefit outweighs risk. Administer to those and others with history of GI disease only under close supervision.

**Precautions:** DO NOT GIVE NAPROSYN (NAPROXEN) CONCOMITANTLY WITH ANAPROX® (NAPROXEN SODIUM) SINCE BOTH CIRCULATE IN PLASMA AS THE NAPROXEN ANION. Because anaphylactic reactions usually occur in patients with a history of such reactions, question patients for asthma, nasal polyps, urticaria, and hypertension associated with NSAIDs before starting therapy. If such symptoms occur, discontinue the drug. Acute interstitial nephritis with hematuria, proteinuria, and nephrotic syndrome has been reported. Patients with impaired renal function, heart failure, liver dysfunction, taking diuretics, and the elderly are at greater risk of overt renal decompensation. If this occurs, discontinue the drug. Use with caution and monitor serum creatinine and/or creatinine clearance in patients with significantly impaired renal function. Use caution in patients with baseline creatinine clearance less than 20 mL/min. Use caution when high doses are required in the elderly or in patients with chronic alcoholic liver disease or cirrhosis. With NSAIDs, borderline elevations of liver tests may occur in up to 15% of patients. They may progress, remain unchanged, or be transient with continued therapy. Elevations of SGPT or SGOT occurred in controlled clinical trials in less than 1% of patients. Severe hepatic reactions, including jaundice and fatal hepatitis, have been reported rarely. If liver disease develops or if systemic manifestations occur (e.g., eosinophilia or rash), discontinue therapy. If steroid dosage is reduced or eliminated during therapy, do so slowly and observe patients closely for adverse effects, including adrenal insufficiency and exacerbation of arthritis symptoms. Discontinue hemoglobin and hematocrit tests for patients with initial values of 10 grams or less who receive long-term therapy. Peripheral edema has been reported. For patients with restricted sodium intake, note that each tablet contains approximately 25 mg (1 mEq) sodium. Use with caution in patients with fluid retention, hypertension or heart failure. The drug's antipyretic and anti-inflammatory activities may reduce fever and inflammation, diminishing their diagnostic value. Conduct ophthalmic studies soon after starting therapy and at periodic intervals if the drug is used for an extended period.

**Information for Patients:** Patients should use caution for activities requiring alertness if they experience drowsiness, dizziness, vertigo or depression during therapy.

**Drug Interactions:** Use caution when giving concomitantly with coumarin-type anticoagulants; hydantoin, sulfonamide or sulfonylureas; furosemide; lithium; beta-blockers; probenecid; or methotrexate.

**Drug/Laboratory Test Interactions:** The drug may decrease platelet aggregation and prolong bleeding time or increase urinary values for 17-ketogenic steroids. Temporarily stop therapy for 72 hours before doing adrenal function tests. The drug may interfere with urinary assays of 5HIAA.

**Carcinogenesis:** A 2-year rat study showed no evidence of carcinogenicity.

**Pregnancy:** Category B. Do not use during pregnancy unless clearly needed. Avoid use during late pregnancy.

**Nursing Mothers:** Avoid use in nursing mothers.

**Pediatric Use:** Indications and dosage have not been established.

**Adverse Reactions:** Incidence Greater Than 1%: GI: The most frequent complaints related to the GI tract: constipation; heartburn; abdominal pain; nausea; dyspepsia, diarrhea, stomatitis. CNS: headache; dizziness; drowsiness; light-headedness, vertigo. Dermatologic: itching (pruritus); skin eruptions; ecchymoses; sweating; purpura. Special Senses: tinnitus; hearing disturbances; visual disturbances. Cardiovascular: edema; dyspnea; palpitations. General: "flu"-like syndrome of reported reaction 3%-9%. Where incidence less than 3%: Incidence Less Than 1%: Probable Causal Relationship: GI: abnormal liver function tests, GI bleeding and/or perforation, hematemesis, jaundice, melena, peptic ulceration with bleeding and/or perforation, vomiting. Renal: glomerular nephritis, hematuria, interstitial nephritis, nephrotic syndrome, renal disease. Hematologic: eosinophilia, granulocytopenia, leukopenia, thrombocytopenia. CNS: depression, dream abnormalities, inability to concentrate, insomnia, malaise, myalgia and muscle weakness. Dermatologic: alopecia, skin rashes. Special Senses: hearing impairment. Cardiovascular: congestive heart failure. Respiratory: eosinophilic pneumonitis. General: anaphylactoid reactions, menstrual disorders, pyrexia (chills and fever). Causal Relationship Unknown: Hematologic: agranulocytosis, aplastic anemia, hemolytic anemia. CNS: cognitive dysfunction. Dermatologic: urticaria. GI: ulcerative stomatitis. General: angioneurotic edema, hyperglycemia, hypoglycemia.

**Overdose:** May have drowsiness, heartburn, indigestion, nausea, vomiting. Empty stomach and use usual supportive measures. Prompt administration of 5 grams activated charcoal may reduce drug absorption.

**Dosage and Administration for Mild to Moderate Pain, Dysmenorrhea and Acute Tendinitis and Bursitis:** The recommended starting dose is two 275 mg tablets, followed by one 275 mg tablet every 6 to 8 hours, as required. The total daily dose should not exceed 5 tablets (1375 mg).

**Caution:** Federal law prohibits dispensing without prescription.

See package insert for full Prescribing Information.

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# Limbitol® (Tranquilizer-Antidepressant)

Before prescribing, please consult complete product information, a summary of which follows:

**Indications:** Relief of moderate to severe depression associated with moderate to severe anxiety.

**Contraindications:** Known hypersensitivity to benzodiazepines or tricyclic antidepressants. Do not use with monoamine oxidase (MAO) inhibitors or within 14 days following discontinuation of MAO inhibitors since hypertensive crises, severe convulsions and deaths have occurred with concomitant use; then initiate cautiously, gradually increasing dosage until optimal response is achieved. Contraindicated during acute recovery phase following myocardial infarction.

**Warnings:** Use with great care in patients with history of urinary retention or angle-closure glaucoma. Severe constipation may occur in patients taking tricyclic antidepressants and anticholinergic-type drugs. Closely supervise cardiovascular patients. (Arrhythmias, sinus tachycardia and prolongation of conduction time reported with use of tricyclic antidepressants, especially high doses. Myocardial infarction and stroke reported with use of this class of drugs.) Caution patients about possible combined effects with alcohol and other CNS depressants and against hazardous occupations requiring complete mental alertness (e.g., operating machinery, driving).

**Usage in Pregnancy:** Use of minor tranquilizers during the first trimester should almost always be avoided because of increased risk of congenital malformations as suggested in several studies. Consider possibility of pregnancy when instituting therapy; advise patients to discuss therapy if they intend to or do become pregnant.

Since physical and psychological dependence to chloridazepoxide have been reported rarely, use caution in administering Limbitol to addiction-prone individuals or those who might increase dosage, withdrawal symptoms following discontinuation of either compound could be severe (nausea, headache and malaise for amitriptyline, symptoms [including convulsions] similar to those of barbiturate withdrawal for chloridazepoxide).

**Precautions:** Use with caution in patients with a history of seizures, in hyperthyroid patients or those on thyroid medication, and in patients with impaired renal or hepatic function. Because of the possibility of suicide in depressed patients, do not permit easy access to large quantities in these patients. Periodic liver function tests and blood counts are recommended during prolonged treatment. Amitriptyline component may block action of guanethidine or similar antihypertensives. When tricyclic antidepressants are used concomitantly with cimetidine (Tagamet), clinically significant effects have been reported involving delayed elimination and increasing steady state concentrations of the tricyclic drugs. Concomitant use of Limbitol with other psychotropic drugs has not been evaluated; additive effects may be additive. Discontinue several days before surgery. Limit concomitant administration of ECT to essential treatment. See Warnings for precautions about pregnancy. Limbitol should not be taken during the nursing period. Not recommended in children under 12. In the elderly and debilitated, limit to smallest effective dosage to preclude ataxia, oversedation, confusion or anticholinergic effects.

**Adverse Reactions:** Most frequently reported are those associated with either component alone: drowsiness, dry mouth, constipation, blurred vision, dizziness and lightheadedness. Less frequently occurring reactions include vivid dreams, impotence, tremor, confusion and nasal congestion. Many depressive symptoms including anorexia, fatigue, weakness, restlessness and lethargy have been reported as side effects of both Limbitol and amitriptyline. Granulocytopenia, jaundice and hepatic dysfunction have been observed rarely. The following list includes adverse reactions not reported with Limbitol but requiring consideration because they have been reported with one or both components or closely related drugs: Cardiovascular: Hypotension, hypertension, tachycardia, palpitations, myocardial infarction, arrhythmias, heart block, stroke. Psychiatric: Euphoria, apprehension, poor concentration, delusions, hallucinations, hypomania and increased or decreased libido.

**Neurologic:** Incoordination, ataxia, numbness, tingling and paresthesias of the extremities, extrapyramidal symptoms, syncope, changes in EEG patterns.

**Anticholinergic:** Disturbance of accommodation, paralytic ileus, urinary retention, dilatation of urinary tract.

**Allergic:** Skin rash, urticaria, photosensitization, edema of face and tongue, pruritus.

**Hematologic:** Bone marrow depression including agranulocytosis, eosinophilia, purpura, thrombocytopenia. **Gastrointestinal:** Nausea, epigastric distress, vomiting, anorexia, stomatitis, peptic ulcer, diarrhea, black tongue. **Endocrine:** Testicular swelling and gynecomastia in the male, breast enlargement, galactorrhea and minor menstrual irregularities in the female, elevation and lowering of blood sugar levels, and syndrome of inappropriate ADH (antidiuretic hormone) secretion.

**Other:** Headache, weight gain or loss, increased perspiration, urinary frequency, mydriasis, jaundice, alopecia, parotid swelling.

**Overdosage:** Immediately hospitalize patient suspected of having taken an overdose. Treatment is symptomatic and supportive. IV administration of 1 to 3 mg physostigmine sulfate has been reported to reverse the symptoms of amitriptyline poisoning. See complete product information for manifestation and treatment.

**Dosage:** Individualize according to symptom severity and patient response. Reduce to smallest effective dosage when satisfactory response is obtained. Larger portion of daily dose may be taken at bedtime. Single h.s. dose may suffice for some patients. Lower dosages are recommended for the elderly.

**Limbitol DS (double strength) Tablets:** initial dosage of three or four tablets daily in divided doses, increased up to six tablets or decreased to two tablets daily as required. **Limbitol Tablets:** initial dosage of three or four tablets daily in divided doses, for patients who do not tolerate higher doses.

**How Supplied:** Double strength (DS) Tablets, white, film-coated, each containing 10 mg chloridazepoxide and 25 mg amitriptyline (as the hydrochloride salt), and Tablets, blue, film-coated, each containing 5 mg chloridazepoxide and 12.5 mg amitriptyline (as the hydrochloride salt). Available in bottles of 100 and 500. Tel-E-Dose® packages of 100. Prescription Packs of 50.



ROCHE PRODUCTS INC.  
Mann, Puerto Rico 00701

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